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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,530	01/23/2004	Minoru Sano	NPR-135	5543
20374	7590	11/16/2005		
KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			EXAMINER MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/762,530	Applicant(s) SANO ET AL.	
	Examiner Melissa A. McCorkle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Examiner's written requirement for an election/restriction has been withdrawn in view of a telephone call made on 9/29/2005, where applicant had previously orally elected Group I, claims 1-6.

As such, the following is a first action on the merits of Group I, claims 1-6.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futagawa et al (5,899,889) in view of Grippi et al (WO 02/102571). Futagawa et al

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discloses a prefilled syringe (fig 1) comprising a shoulder portion (33) with a luer tip (110) arranged to be connected to an injection needle (11) at a tip (110), a barrel (1) closed by the shoulder and having an open proximal end (fig 4), and a gasket (col 7 lines 49-50), and a medication (S). Futagawa et al does not disclose the barrel having a multilayer structure in which an innermost and an outermost layer are both made of a polyolefin resin, and an intermediate layer is sandwiched by the innermost layer and the outmost layer and is composed of at least one layer made of a resin excelling in a barrier property, wherein the intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip; an end of the intermediate layer in a cylindrical wall portion of the barrel formed up to a rim of the shoulder portion; the shoulder portion formed with the polyolefin resin having a thickness sufficient to exert a barrier property, the intermediate layer not being formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel. Grippi et al shows these features to be old in the syringe art. It would have been obvious to one ordinary skill in the art at the time of applicant's invention to modify the prefilled syringe of Futagawa et al from the teaching of Grippi et al to replace the barrel of Futagawa with the barrel of Grippi et al in order to inhibit passage of atmospheric gases through the polymer wall of the barrel.

5. Grippi et al discloses the barrel (fig 1) having a multilayer structure (0009) in which an innermost and an outermost layer are both made of a polyolefin resin (0025) and an intermediate layer is sandwiched by the innermost layer and the outmost layer and is composed of at least one layer made of a resin excelling in a barrier property

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(0025-0027), wherein the intermediate layer (fig 5 and 6) is capable of being formed up to a vicinity of a surface of the tip of the luer tip (0032-0033); an end of the intermediate layer (fig 5 and 6) in a cylindrical wall portion (fig 4) of the barrel is capable of being formed up to a rim of the shoulder portion; the shoulder portion formed with the polyolefin resin having a thickness sufficient to exert a barrier property (0025-0027), the intermediate layer (fig 5 and 6) is capable of not being formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel (0032-0033).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fukui et al (US 6,544,233) discloses a pre-filled syringe; Kolberg et al (US 6,053,895) discloses a syringe with new and improved plug; Keller (US 3,375,825) discloses a prefilled syringe; Sudo et al (US 2003/0032928) discloses a prefilled syringe assembly.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNICAL SERVICES DIVISION

Melissa A McCorkle
Examiner
Art Unit 3763

MAM
10/18/2005